

## **REMARKS/ARGUMENTS**

### **Status of the Claims**

Upon entry of the present amendment, claims 5, 7-9 and 23-28 are pending. Claims 1, 3-4 and 10-22 are canceled without disclaimer or prejudice to renewal. Claims 5, 7-9 and 23 are amended. Claims 24-28 are newly added.

Claims 5 and 7-8 and 23 are amended in accordance with the suggestions of the Examiner to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted, wherein the nonapeptide binds to an HLA-A 0201 restricted T cell receptor with high affinity and induces a high CTL response. Support is found, for example, on page 8, lines 18-27; on page 9, lines 2-14; and throughout the specification.

Claim 9 is amended to set forth a composition comprising one or more of the peptides of the invention.

Support for new claim 24 is found, for example, on page 8, lines 18-27.

Support for new claims 25 and 26 are found, for example, in the abstract and on page 2, lines 28-29; on page 8, lines 18-27; on page 9, lines 2-14; and throughout the specification.

Support for new claim 27 is found, for example, on page 10, lines 12-22.

Support for new claim 28 is found, for example, on page 10, lines 23-27.

No new matter is added by the present amendments, and the Examiner is respectfully requested to enter them.

### **Telephonic Interview**

The Examiner is thanked for graciously granting the telephonic interview of September 16, 2008. The issues discussed are set forth in the present Office Action and in the present response.

**Rejection under 35 U.S.C. § 112, first paragraph, enablement**

The Examiner has rejected claims 5, 7-10 and 20-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

With respect to claim 5, the Examiner objected to the recitation of open language and the absence of recitation of function. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and having the function of binding to an HLA-A 0201 restricted T cell receptor with high affinity and inducing a high CTL response. Applicants submit that amended claim 5 is presently in accordance with what the Examiner considers enabled by the present specification. *See*, page 2 of the present Office Action.

With respect to claim 7, the Examiner objected to the open language of independent claim 5, and to the recitation of methionine. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 7 to set forth that the second amino acid from the N terminus is leucine or isoleucine. As discussed in the previous response, the nonapeptide of SEQ ID NO:30 has isoleucine as the second amino acid from the N terminus, and the nonapeptide of SEQ ID NO:54 has leucine as the second amino acid from the N terminus. The Examiner depicts the relationship between SEQ ID NO:30 and SEQ ID NO:54 on page 8 of the present Office Action.

With respect to claim 8, the Examiner objected to the open language of independent claim 5, and to the recitation of valine. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 8 to set forth that the C-terminal amino acid is leucine. The C-terminal amino acid of the nonapeptides of SEQ ID NO:30 and SEQ ID NO:54 is leucine.

With respect to claim 9, the Examiner objected to the claim reciting treating or preventing tumors. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 9 to remove the objected language.

The Examiner's objections to claims 10 and 20-22 are obviated by cancellation of these claims.

With respect to claim 23, the Examiner objected to reference to an amino acid sequence of SEQ ID NO:54. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 23 to set forth the amino acid sequence of SEQ ID NO:54.

Applicants respectfully submit that those of skill in the art would be able to make and use the present invention commensurate with the scope of the claims. Applicants further believe that the amended claims are commensurate in scope with what the Examiner expressly states to be enabled on page 2 of the present Office Action. Accordingly, the Examiner is respectfully requested to withdraw the present rejection.

**Rejection under 35 U.S.C. § 112, first paragraph, written description**

The Examiner has rejected claims 5, 7-10 and 20-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

With respect to claim 5, the Examiner objected to the recitation of open language and the absence of recitation of function. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and having the function of binding to an HLA-A 0201 restricted T cell receptor with high affinity and inducing a high CTL response. Applicants submit that amended claim 5 is presently in accordance with what the Examiner considers enabled by the present specification. *See*, page 2 of the present Office Action.

With respect to claim 7, the Examiner objected to the open language of independent claim 5, and to the recitation of methionine. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 7 to set forth that the second amino acid from the N terminus is leucine or isoleucine. As the Examiner acknowledges on page 8 of the present Office Action, the nonapeptide of SEQ ID

NO:30 has isoleucine as the second amino acid from the N terminus, and the nonapeptide of SEQ ID NO:54 has leucine as the second amino acid from the N terminus.

With respect to claim 8, the Examiner objected to the open language of independent claim 5, and to the recitation of valine. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 8 to set forth that the C-terminal amino acid is leucine. The C-terminal amino acid of the nonapeptides of SEQ ID NO:30 and SEQ ID NO:54 is leucine.

With respect to claim 9, the Examiner objected to the claim reciting treating or preventing tumors. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 9 to remove the objected language.

The Examiner's objections to claims 10 and 20-22 are obviated by cancellation of these claims.

With respect to claim 23, the Examiner objected to reference to an amino acid sequence of SEQ ID NO:54. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 23 to set forth the amino acid sequence of SEQ ID NO:54.

Applicants respectfully submit that the nonapeptides of SEQ ID NO:30 and SEQ ID NO:54 are representative of the genus of nonapeptides that is structurally defined as a nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and is functionally defined as having the ability to bind to an HLA-A0201 restricted T cell receptor with high affinity and induce a high CTL response. As the Examiner acknowledges, Applicants have shown that the nonapeptides of SEQ ID NO:30 and SEQ ID NO:54 can retain their function of binding to an HLA-A0201 restricted T cell receptor with high affinity and inducing a high CTL response with at least one substituted amino acid, *e.g.*, at the second amino acid from the N terminus. *See, e.g.*, page 8 of the present Office Action; Example 13 on page 23, line 26 through page 24, line 6 and Examples 18-20 on page 25, line 31 through page 26, line 22 of the Specification.

In view of the foregoing, Applicants respectfully submit that those of skill in the art would recognize that Applicants have conveyed possession of the invention in the specification as filed commensurate with the scope of the claims. Accordingly, the Examiner is respectfully requested to withdraw the present rejection.

**Rejection under 35 U.S.C. § 102(b) over Flamme**

The Examiner has rejected claims 5 and 8 under 35 U.S.C. § 102(b) as allegedly anticipated by Flamme, *et al.*, *Developmental Biology* (1995) 169:699-712 (“Flamme”). Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to remove to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and having the function of binding to an HLA-A 0201 restricted T cell receptor with high affinity and inducing a high CTL response. Flamme does not teach or suggest a nonapeptide of the present invention. Accordingly, the Examiner is respectfully requested to withdraw the present rejection.

**Rejection under 35 U.S.C. § 102(b) over U.S. Patent No. 5,712,380**

The Examiner has rejected claims 5 and 8 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,712,380 (“the ‘380 patent”). Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to remove to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and having the function of binding to an HLA-A 0201 restricted T cell receptor with high affinity and inducing a high CTL response. The ‘380 patent does not teach or suggest a nonapeptide of the present invention. Accordingly, the Examiner is respectfully requested to withdraw the present rejection.

**Rejection under 35 U.S.C. § 102(b) over Kubo**

The Examiner has rejected claims 5 and 8 under 35 U.S.C. § 102(b) as allegedly anticipated by Kubo, *et al.*, *J Immunol* (1994) 152:3913-3921 ("Kubo"). Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to remove to set forth an isolated nonapeptide consisting of SEQ ID NO:30 or SEQ ID NO:54 wherein zero, one or two amino acids have been substituted and having the function of binding to an HLA-A 0201 restricted T cell receptor with high affinity and inducing a high CTL response. Kubo does not teach or suggest a nonapeptide of the present invention. Accordingly, the Examiner is respectfully requested to withdraw the present rejection.

**Rejection under 35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 5 and 7 under 35 U.S.C. § 112, second paragraph, as allegedly unclear. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 5 to set forth proper Markush language and that the genus of nonapeptides can have zero, one or two amino acid substitutions. Claim 7 is amended to set forth that the second amino acid from the N terminus is leucine or isoleucine. Applicants submit that claim 7 properly depends from claim 5. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

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Amdt. dated September 30, 2008  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group 1644

PATENT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Jennifer L. Wahlsten  
Reg. No. 46,226

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 415-576-0200  
Fax: 415-576-0300  
Attachments  
J1W:j1w  
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